5.4.1 Identify and Describe Use Scenarios Resulting in Hazards

Two perspectives are necessary to identify and describe use scenarios that could result in hazards. The "top-down" perspective identifies possible hazards first, then the analyst determines all the possible use scenarios that could lead to that hazard. The "bottom-up" perspective begins with known, likely, or suspected use scenarios that involve difficulty using a device prototype, similar devices or similar components, and then determines the hazards that can result from these problems analytically.

The best source of information on use-related hazards associated with similar devices (known hazards) is likely to be complaint and customer feedback files. Other sources of information on known hazards are discussion (focus groups) with device users, journal articles, proceedings of professional meetings, newsletters, and relevant internet sites, such as:

- FDA's Medical Device Reporting data files (http://www.fda.gov/cdrh/mdrfile.html),
- FDA's Manufacturer and User Facility Device Experience Database (http://www.fda.gov/cdrh/maude.html),
- CDRH Safety Alerts, Public Health Advisories, and Notices (http://www.fda.gov/cdrh/safety.html)
- FDA Enforcement Reports – recalls and legal actions (http://www.fda.gov/opacom/Enforce.html)
- ECRI's Medical Device Safety Reports (http://www.mdsr.ecri.org/index.html),
- The Institute of Safe Medical Practices (ISMP's) Medication Safety Alert (http://www.ismp.org/ISMP/MSAarticles/msa_past.html), and
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO's) Sentinel Events (http://wwwb.jcaho.org/sentinel/sentevnt_main.html).

The *device use description* (see Section 5.1) and *task analyses* provide information to help the analyst identify and describe use-related hazards. With respect to the overall HFE process, use scenarios identified from this analysis can be thought of as anticipated use scenarios. Unanticipated use scenarios that result in hazards are identified and described through the application of empirical approaches such as *usability testing* (see Section 5.5).

Answering the following questions can help identify and describe potential scenarios that could result in hazards (Note: This list is not exhaustive):

1. Why have problems occurred with the use of other similar products?
2. What are the critical steps in setting-up and operating the device? Can they be performed adequately by the expected users? How might the user set the device up incorrectly and what effects would this have?
3. Is the user likely to operate the device differently than the instructions indicate?
4. Is the user or use environment likely to be different than that originally intended?
5. How might the physical and mental capabilities of users affect their use of the device?
6. Are users likely to be affected by clinical or age-related conditions that impact their physical or mental abilities and could affect their ability to use the device?
7. How might safety-critical tasks be performed incorrectly and what effects would this have?
8. How important is user training, and will users be able to operate the device safely and effectively if they don't have it?
9. How important are storage and maintenance recommendations for proper device function, and what might happen if they are not followed?
10. Do any aspects of device use seem complex, and how can the operator become "confused" when using the device?
11. Are the auditory and visual warnings effective for all users and use environments?
12. To what extent will the user depend on device output or displayed instructions for adjusting medication or taking other health-related actions?
13. What will happen if necessary device accessories are expired, damaged, missing, or otherwise different than recommended?
14. Is device operation reasonably resistant to everyday handling?
15. Can touching or handling the device harm the user or patient?
16. If the device fails, does it "fail safe" or give the user sufficient indication of the failure?
17. Could device use be affected if power is lost or disconnected (inadvertently or purposefully), or if its battery is damaged, missing or discharged?

5.4.2 Function and Task Analyses

Descriptions of exactly what *functions* and *tasks* are vary among function and task analysis techniques available. These differences are not critical; the important contribution of applying function or task analysis techniques is the systematic breakdown of the device-use process into discrete steps or sequences for the purposes of description and further analysis. With respect to safety, function and task analyses can contribute by:

- Identifying critical aspects of device use potentially resulting in hazards to users and patients,
- Providing a basis for the analysis of use-related hazards, and
- Evaluating known incidents or accidents to understand what led to the problem.

A simplistic example of a task analysis component for a hand-held blood glucose meter includes the following tasks:

1. Patient's finger is lanced with automatic lancing device (device +user)
2. Blood sample is placed on test strip (user)
3. Test strip is placed in device (user)
4. The sample is allowed to react with reagents in the test strip for a specific time (device+user)
5. Blood glucose level in the sample is measured (device)
6. The resulting value is displayed (device)
7. The displayed value is read, interpreted, and acted upon (user)

This set of tasks includes examples that are performed by the "user" by the "device" or by a combination of the user and the device ("user+device").

After functions and tasks have been identified, they are analyzed to determine if, and how HF considerations apply. For instance, in Task 2 above, the user places a sample of blood on a test strip. There are five fundamental questions that should be investigated:

1. *Are any use-related hazards scenarios possible?*
2. *How might they occur?*
3. *How likely are they?*
4. *What are the possible consequences of each?*
5. *How might they be prevented?*

To begin to address these, the analyst should pose more specific questions, such as:

- How difficult is it for users to use the device components and accessories to do this task correctly?
- How much effort is required by the user to apply a sample correctly?
- What characteristics of the user population might cause some users to have difficulty with this task?
- Where will the testing be done, and could ambient conditions effect the test results or the users ability to perform the task?
- Is the proper use of test strips evident to the user?
- Will certain user interactions with the device degrade the accuracy, safety and effectiveness of the devices' subsequent operations (and if so, what are these interactions and how are device operations affected)?

In early glucose monitors, the user had to perform Task #4 manually (the sample is allowed to react with reagents in the test strip for a specific time). Users had difficulty doing this task well, and the accuracy of the results too often suffered from the users' failure to time the process accurately. In subsequent models, this task was done automatically by the device. Modification in device design and operation removed that use scenario and the resulting hazard.

Analyzing functions and tasks in this way will allow identification of possible hazards associated with device use. Function and task analyses can provide a foundation for subsequent HFE efforts. For instance, *test scenarios* (see Section 5.5) should be developed to address *use scenarios* that involve tasks identified as critical or error-prone.

5.4.3 Heuristic Analysis

Heuristic analysis is an analytic process in which the device's user-interface is formally evaluated from the perspective of users. The object is to identify possible use-related hazards with a focus on the interaction of the user with the user interface and operating logic of the device. Design team members often perform heuristic evaluations, but they are more effective if they involve clinical and HFE personnel. This technique is particularly useful for early identification of difficult or counter-intuitive aspects of the device user interface. Another application is the evaluation of candidate interface design alternatives. The output of heuristic analysis is limited because evaluators typically do not represent real users, use scenarios considered might not be comprehensive, and the evaluation environment is not representative of actual use.

Heuristic analyses should include careful consideration of accepted concepts for design and operation of the user interface, sometimes known as "de-facto" standards or "population stereotypes" which are essentially social and cultural norms and constraints for the use of device components. A simple example is a light switch oriented in a vertical direction being "on" when it is in the "up" position and "off" when in the "down position". For medical devices, general de-facto standards are applicable at times, while others are unique for certain kinds, or types, of medical devices.

5.4.4 Expert Review

Expert reviews rely on clinical and HF experts to analyze device use, identify problems, and make recommendations for addressing them. The process is quite similar to the heuristic analyses. The difference is that expert review relies more heavily on the assessment of individuals with expertise in a specific area. The success of the expert review depends on the expert's knowledge of the device technology, its use, clinical perspectives, characteristics of the intended users, as well as the expert's ability to predict actual device use. This kind of review can provide very useful information, particularly early in the design process, but might not be comprehensive since it does not involve actual device use and might not include the perspective of actual users.

5.5 Empirical HFE Approaches (Use Studies)

Use studies are applicable to several risk management activities. They can be used early in the design process to identify unanticipated use-related hazards. They can also be used to clarify suspected or known problems with device use, demonstrate that use-related hazards have been addressed, evaluate candidate design alternatives, and to validate safe and effective use by intended users. Beyond application to the safety and effectiveness of device use, use studies provide a powerful means for creating effective labeling (including directions for use), and device designs that are user friendly, satisfying to use, and desirable to users. For the consideration of device use-related risks to be complete, empirical methodologies should include efforts that focus on identification and analysis of unanticipated use-related hazards and the incorporation of the results into the overall risk management process. *Use Studies can identify problems that were noticed by test participants but did not manifest themselves as errors during use.*

Use studies will provide accurate results to the extent that test participants represent actual device users, the test conditions represent realistic use environments, and the test is well run. Members of the team who are developing the device should not participate as users since their knowledge of how the device operates (or should operate) will influence how they use it. If the intended users have certain limitations in their abilities, one focus of the testing should be to establish whether these limitations affect device use. If so, further effort is required to determine whether potential use problems associated with user limitations can be mitigated by modifying the design of the device interface or the operation of the device.

Although user studies are effective in identifying and understanding device use, care should be taken not to underestimate the frequency of problems based on the experiences of test participants. Participants could be (despite good efforts of test coordinators) unrealistically well trained, capable, or careful. Also, when people are observed they often try to "do their best" and often do not use the device long enough to experience infrequent problems.

When applied to medical devices, empirical approaches should support identification, understanding, and mitigation of hazards resulting from device use. *Demonstrating how well users like using a device is not sufficient to do this.* However, both use-safety *and* user preference can be addressed through proper application of empirical approaches.

5.5.1 Walk-Through

A simple kind of study involving users is the *walk-through.* It is less time-consuming and less formal than Usability Testing. In a walk-through, a user or small group of users are "walked-through" the process of using a device. During the walk-through, participants are questioned and encouraged to provide feedback on difficulties they notice while using the device. Evaluators can also collect subjective information from participants about thought processes, mental models, and perceived workload when using the device. The walk-through technique can provide valuable information but is limited by a lack of realism. The walk-through technique is most useful early in the development process, and for developing and evaluating usability testing scenarios.

5.5.2 Usability Testing

Usability testing (also called *user testing*) is a powerful technique used to assess user's interaction with a product. This technique can also be used to identify and understand previously unanticipated or poorly understood use scenarios resulting in hazards if care is taken to focus on the safety and effectiveness perspectives. The central advantage of usability testing is that device use is realistic and the results of the process are more representative of actual use than results obtained through analytic approaches. If usability testing is employed early in the development process, it can identify potential use-related hazards so that they can be addressed early in the design life cycle.

Usability testing involves systematic collection of data from users (participants) using a device (or device component) in realistic situations. Data are obtained in a variety of ways, including user feedback, manual and automated measures of user performance, and observation. Often, the most convenient data collection methods focus on subjective user feedback. User feedback includes descriptions by test participants of difficulties encountered, good and bad aspects of the device user interface characteristics, including the logic of device operation, and suggested changes. Careful collection of subjective assessment of device use can identify problems that were noticed by test participants ("concerns," or "close calls") but did not manifest themselves as errors during use and not identified in objective performance measures.

Objective user performance measures include the type and number of errors, time required to do tasks, requests for help, accuracy, and the success or failure on individual tasks and overall performance. The application of specific, objective user performance measures enhances and focuses subjective user feedback. Performance measures are particularly useful for complex devices, where users might not be aware of (and therefore unable to evaluate) potentially hazardous use scenarios. These measures are also important for home-use devices where users are often not aware that they are inadvertently effecting the performance or accuracy of the device in some way. Outlier data from performance measures is often informative and should be investigated to determine the nature and pattern of the use scenarios associated with them.

Usability testing can be done in a variety of ways in various degrees of complexity and formality. However it is done, it should include the following:

- An overall goal of improving the usability, including safe and effective device use,
- Test participants represent intended users,
- Test participants do real tasks, particularly tasks that will indicate whether safe and effective use is achieved,
- A focus on high risk use scenarios,
- Testers who observe and record important aspects of what test participants do and say (participants can also respond to questionnaires, or be interviewed following the use of the device), and
- Data collected to support the identification of potential use-related hazards and the development of specific recommendations to address them.

The validity of use testing depends on the extent to which realistic or simulated environments are used during the testing. For example, in clinical settings users must perform multiple tasks simultaneously. These tasks involve individual devices, multiple devices, and duties unrelated to device use. Users must constantly trade-off accuracy for speed. In home environments, users might be distracted or have medical conditions that affect their abilities to interact with the device. Home users can also drop devices or expose them to various temperatures and humidity levels in various parts of the home. Clinical and home users might try to cut costs. There are many aspects of the use environment that can affect device use. By the time use testing is undertaken, anticipated use environments should be understood (*device use description*).

5.6 Prioritize and Assess Use-Related Hazards

Use-related hazards identified by analytic and empirical approaches should be assessed to determine their priority for subsequent risk control efforts. This process can involve obtaining and combining input from several individuals who provide perspective from a variety of areas of expertise. In addition, it should also incorporate valid and useful information about likelihood and consequences (i.e., risk) of use-related hazards for similar devices when available.

Important perspectives include those from:

- Clinical experts,
- Expert users,
- Engineers involved with design and operation, and
- HFE or usability specialists.

These individuals should then assess the likelihood of these hazards and their consequences to estimate the risk for each. Within the general process described in this guidance, assessing preliminary results through group consensus is most useful for:

- Identifying hazards for which mitigation is necessary,
- Identifying hazards that have been successfully addressed,
- Developing strategies and controls to eliminate, reduce the likelihood of, or mitigate the consequences of use-related hazards, and
- Verifying that controls are effective in reducing or eliminating hazards.

5.7 Mitigate and Control Use-Related Hazards

Identifying and addressing use-related hazards early in the design process reduces the time and expense necessary to correct them. The most effective strategies to address use-related hazards focus on improvements to the design of the device user interface. The user interface should convey the concept for correct operation through its appearance and operation ("look and feel") so that safe and effective use is intuitive. Addressing use-related hazards through this kind of modification is preferred because it reduces or eliminates the need for users to rely on instructions, labeling, or training "patches."

Use-related hazards often require a combination of mitigation and control strategies. The following list presents the order of overall priority for applying strategies to control or mitigate risks of use-related hazards:

1. **Modify device design to remove hazard or reduce its consequences:** Making the interface intuitive and ensuring that critical information is effectively communicated to the user can reduce the likelihood or eliminate certain use-related hazards. If hazards cannot be eliminated, the design should act to mitigate the consequences.

2. **Make user interface, including operating logic, error tolerant (safety features):** When users can make errors using the device, such as pressing an adjacent key on a keypad, the device should act to preclude a hazardous outcome from occurring. Safety mechanisms such as physical safety guards, shielded controls, or software or hardware interlocks will make the design more tolerant of errors that users occasionally make.

3. **Alert users to the hazard:** When neither design nor safety features will effectively eliminate a use-related hazard or mitigate the consequences, the device should detect the condition and provide an adequate warning signal to alert users.

4. **Develop written procedures and training for safe operation:** Where it is impossible to eliminate hazards through any of the previous strategies, or to enhance other control or mitigation strategies, written procedures, labeling enhancements, and training for safe operation should be used.

Instructions, labeling, and training can influence users to use devices safely and effectively and are critical HFE considerations for safe device use. But because they rely on the user to consistently use the device as directed, these approaches are less effective than modifications to the design of the user interface. Therefore, mitigation of use-related hazards should not focus on instruction, labeling, or training fixes in isolation, since these "patches" might not be adequate. Often, a combination of these strategies is the best solution. Regardless of the strategy used, subsequent testing should be done to ensure that the use-related hazards have been successfully controlled.

5.8 Verify and Validate User Interface Design

Verification confirms that the specific functional and operational requirements for the design of a device user interface have been met. The process for verifying individual user interface requirements will likely require focused effort for each. For instance, if a device will be used by a user population of elderly users with hearing ability ranging from normal to moderate impairment, a specification should be developed to assure that the device's alarm volume can be adjustable to a sufficient level to accommodate these users. The verification process would involve testing the device alarm to ensure that the volume adjustment capability (and any other specifications developed to assist users) has been implemented successfully.

Validation establishes that the device meets the needs of the intended users. The primary need of medical device users is the ability to use the devices safely and effectively under the actual use conditions. Applying usability testing approaches can directly validate a user interface design. For the purpose of validation, it is particularly important to use a production version of the device, representative device users, actual or simulated use environments, and to address all aspects of intended use. If small-scale iterative testing of interface components is done adequately as the device was developed, it might not be necessary for validation efforts to be extensive at the end of the design process. However, some degree of testing of the entire system under realistic conditions with representative users is warranted. In the alarm volume example above, determining whether users with moderate hearing loss can hear the alarm well enough to allow them to use the device safely and effectively is the essential component of validation of this user interface requirement.

6.0 Document Risk Management Activities for Device Use

Documenting the incorporation of human factors engineering (HFE) in risk management can help demonstrate that a manufacturer has adequately addressed the needs of the intended users. Submitting this documentation can streamline and facilitate that part of the pre-market review process concerned with safe and effective *device use*.

When information pertaining to device use safety is extensive, it is helpful to provide it in summary form that highlights the most important issues, considerations, resolutions, and conclusions. *When portions of this information are contained in various parts of a submission a comprehensive cross-reference should be provided.*

The level of detail of device use documentation submitted should be consistent with the level of concern of use-related hazards for the device. The information that should be included with the device use documentation is described below.

6.1 Device Overall

- The purpose and operation of the device,
- The patient populations *on* whom the device will be used,
- The physical device, e.g., size, shape, weight, important components, and how it is powered,
- A comparison of device use with other devices currently in use that operate similarly or perform similar tasks, and
- A description of how the device addresses the needs of intended users.

6.2 Device User Interface

- The physical characteristics of the user interface,
- The operating logic of the user interface, and
- Existing or anticipated labeling materials that will be provided to the user with the device, e.g., labels on the device itself, packaging, operating instructions, and training materials.

6.3 Device Use

- How the user interacts with the device user interface,
- How the device is set up and maintained, and
- The primary tasks that the user is expected to perform.

6.4 Device User Population

- The intended population of device users,
- The characteristics of device user population that were considered during the design,
- The training and information tools that the user population will require to operate the device safely and effectively, and
- The population of users for which the device is not intended to be used.

6.5 Device Use Environments

- Environments for which the device is intended to be used (e.g., home, hospital, medevac vehicles),and
- Environments for which the device is unsuited, or which can be expected to affect device performance.

6.6 Use-Related Hazards

- The use-related hazards that have occurred with similar, already marketed, devices,
- The processes used to identify and prioritize use-related hazards,
- The use-related hazards that have either been identified during development or have occurred with this device during early testing,
- How significant use-related hazards were mitigated or controlled during design and development, and
- Why strategies used to address use-related hazards are appropriate.

6.7 Verification and Validation

- Testing and evaluation processes and results associated with determining whether device use design considerations have been achieved, and
- Testing and evaluation processes and results associated with determining whether intended device users can use the device safely and effectively in actual or simulated conditions.

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企業ならびにFDAの市販前・設計管理審査担当者向け指針

医療用具の使用－安全性：
リスクマネジメントへの人間工学の取り入れ

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この文書を1999年8月3日付の「医療用具の使用における安全性：
リスクマネジメントへの人間工学の取り入れ」と題する指針文書草案と差し換える。

（米）保健福祉省

（米）食品医薬品局

医療用具・放射線健康管理センター

(Center for Devices and Radiological Health)

Division of Medical Devices User Programs and System Analysis

Office of Healthe and Industry Programs

緒言

パブリックコメント

当局の検討を要する意見および提案は、いつでも受け付ける。連絡先は、Ron Kaye または Jay Crowley（1350 Piccard Dr.（HFZ 230）, Rockvill, Md 20850）。この文書が改訂または更新されるまでは、当局が意見に対して具体的な処置をとることはない。この指針の使用または解釈に関する疑問点があれば、Ron Kaye または Jay Crowley まで電話（301）443 - 2436、または電子メール HFSO@cdrh.fda.gov.で連絡されたい。

複本：

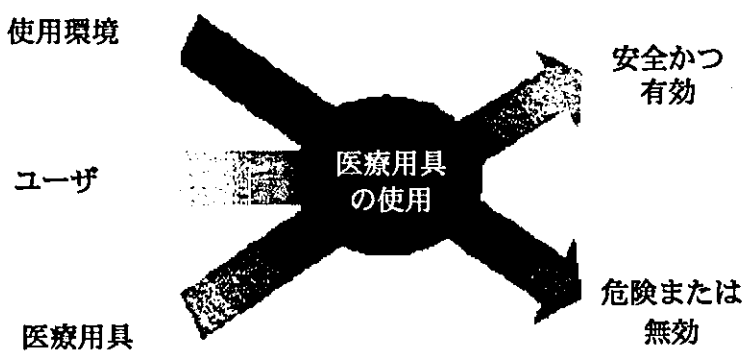
複本は Center for Devices and Radiological Health（CDRH）のウェブサイト http://www.fda.gov/cdrh/HumanFactors.html または CDRH の Facts-on-Demand（1-800-899-0381 または 301-827-0111）（文書の保管番号の質問では 1497 と指定する）により入手可能である。

医療用具の使用－安全性：リスクマネジメントへの人間工学の取り入れ

医療用具の使用に関連するハザードの特定、理解、および対処

著者： Ron Kayte

Jay Crowley



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Division of Device User Programs andSystems Analysis

目次

ページ

医療用具の使用－安全性：
リスクマネジメントへの人間工学の取り入れ

1.0 序文

この指針[1]では、リスクマネジメントプロセスの一部として、医療用具開発中の医療用具の使用に関連するハザードにどのように対処すべきかを説明する。起きる可能性のある使用に関連するハザードを特定し、これに対処する上で最善の方法は、人間工学（HFE）[2]を用いることである。これらの手法をリスクマネジメントプロセスに取り入れる過程について説明する。これらの取り組みを記録することにより、医療用具製造業者が使用に関連するハザードを管理するための努力を行ったことが実証される。最終目標は、使用に関連するハザードを最小限に留めること、製品寿命サイクルを通して対象とするユーザが医療用具を安全かつ有効に使用できるよう保証すること、および新規医療用具の申請と設計管理資料の審査の迅速化を図ることである。

使用に関連するハザードへの対処は、ある医療用具がどのように使用されるかを完全に理解した上で行われるべきである。理解すべき必須項目は以下のとおりである：

- 医療用具ユーザ（すなわち、患者、患者の家族、医師、看護師、介護従事者）、
- 標準的および非標準的な医療用具の使用、
- 医療用具の特性、
- 医療用具の使用が予想される環境の特性、および
- ユーザ、医療用具、および使用環境の相互作用

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[1]本文書は指針を与えることを目的としており、表題に対する当局の現在の考え方を示したものである。いずれかの人物に何らかの権限を設定したり授与したりするものではなく、FDAまたは一般の人々に義務を負わせるものでもない。適用可能な法規、規制、またはその両者の要件を満たす代替法があれば、それを用いても良い。

[2]本文書では、人間工学という用語およびその頭文字を用いた略語（HFE）が広範囲で使用されている。ヒューマンファクタ（HF）という用語も使用される。この2つの用語は、応用（HFE）と科学原理およびその基礎となる学術研究（HF）を区別するために用いられる。

医療用具の使用について完全に理解したら、ハザードを起こし易い医療用具の特殊な使用法について、分析および試験により特定および調査すべきである。医療用具の使用に伴って生じることがわかっている問題、あるいは伴って生じると疑われる問題について調べる他、ユーザを対象として医療用具のプロトタイプの試験を行うことにより、ハザードを起こし得る予想外の医療用具の使用方法を特定できる。医療用具の使用に関する全ての重大問題を事前に特定することは極めて難しいため、この試験は重要である。

使用に関連するハザードについて理解したら、医療用具のユーザインターフェース（コントロールまたは表示に関する特性、操作理論、ラベリングなど）を変更する、あるいはユーザの医療用具使用能力を変更する（トレーニング、使用を有資格ユーザのみに制限など）ことによって、それらのハザードを軽減またはコントロールする。ヒューマンファクタは、使用に関連する問題を特定、理解し、これに対処する上で役立つ、様々な有用な方法を提供する。

本指針は特定の種類の医療用具に焦点を合わせたものではなく、ユーザとの相互作用（思考、認知、意思決定、および手動操作など）に関与する全ての医療用具および付属品に適用されるものである。本指針は、医療用具製造業者、ならびに食品医薬品局（FDA）のCenter for Devices and Radiological Health（CDRH）の市販前申請・設計管理の審査担当者を対象としたものであり、使用に関連するハザードに関する市販後調査活動のための一般的な参考資料となることを意図したものである。読者に設計管理、リスクマネジメントおよびHFEについてのある程度の知識があることを想定している。一部読者には、セクション7.0に挙げる参照文献10、6、19、28、および33が役立つものと思われる。

1.1 使用に関連するハザード

ハザードとは、潜在的な危険源である。ハザードは、医療に固有のリスクを原因として、あるいは医療用具の不具合（または機能異常）や医療用具の使用を原因として、医療用具使用時に生じる。医療用具を原因とするハザードは、患者、患者の家族、および医療提供者に影響を与える。本文書では、ユーザと医療用具との相互作用に起因するハザードについて取り上げ、医療に固有のハザードまたは医療用具の不具合を原因とするハザードを重

点的に取り上げることはない。

医療用具の使用に関連するハザードは、頻度の高い、深刻な問題である[3]。研究者ら（Cooper、Leape、およびその他）の挙げる証拠からは、医療用具の使用に起因するハザードは医療用具の不具合から生じるハザードよりもはるかに多いと考えられる。従って、すべてのハザードが効果的にコントロールされている場合、最も重要なのは、医療用具の安全かつ有効な使用が確実に行われるようにすることである。1999 年 11 月に公開された Institute of Medicine の報告書（参考文献 19、セクション 7.0）は、ある一年間に 98,000 人もの人々が病院で起きる医療過誤により死亡すると算定している。この数は、交通事故、肺癌、あるいは AIDS による死者の数より多い。これらの過誤の多くは医療用具の使用に直接関連するものではないが、一部は直接関連しており、医療用具に関連する医療過誤を減らすために、HFE の原理を医療用具の設計に取り入れることの重要性が強調されている。

医療用具設計者は、信頼性の高い医療用具の開発に関心を持っている。そうした医療用具を開発するため、彼らは医療用具およびその構成要素の不具合によってハザードが生じる可能性を考慮している。この種の不具合は従来の信頼性分析により特定される。設計者は、医療用具の使用について、より完全かつ正確に理解していなければならず、医療用具ユーザ特有の制限や故障モードについても、これらを医療用具－ユーザシステムの極めて重大な成分として、配慮する取り組みが必要とされる。設計者が配慮するのは、使用上の問題の中で最も明白な例（出火や爆発など）や既知の例以外の、医療用具の不具合の原因となり得る比較的少数のユーザの行動についてである。医療用具の設計においてこのような制限があると、予期しない使用シナリオ（セクション 1.2 参照）が生じる可能性や、ユーザおよび患者に対し使用に関連するハザードが生じる可能性が増加する。

リスク分析において通常考慮されるハザードには、次のようなものがある：

- 化学的ハザード（例、有毒化学物質）、
- 機械的ハザード（例、動く物体からの機械的または位置エネルギー）、

[3]医療用具の使い方に起因する死亡および重篤な傷害、FDA の医療用具報告（MDR）プログラムの下で“ユーザエラー”は報告すべき事象とされている。